

08/909,879



UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/909,879 08/12/97 PRIEELS

J 04012.0188

EXAMINER

HM12/0329

FINNEGAN HENDERSON FARABOW  
 GARRETT AND DUNNER  
 1300 I STREET NW  
 WASHINGTON DC 20005-3315

BUDENS, R	PAPER NUMBER
ART UNIT	

1645

DATE MAILED: 03/29/00

This is a communication from the examiner in charge of your application.  
 COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 1/14/00

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 19-20, 23-24 is/are pending in the application.  
 Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 19-20, 23-24 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) 08/356,372

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

Certified copies not received: \_\_\_\_\_

\*knowledge is made of a claim for domestic priority under 35 U.S.C. § 119(e).

ment(s)

once Cited, PTO-892

Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Review, PTO-948

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ACTION ON THE FOLLOWING PAGES--

Serial No. 08/909,879  
Art Unit 1645

The Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

5           The status of the related application(s) cited at the first page of the specification should be updated, if necessary, to ensure a properly completed file record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10           The Examiner acknowledges Applicant's Amendment, Paper No. 42, filed January 14, 2000. In view of Applicant's Amendment, the status of the claims is as follows: Claims 1-18, 21-22 and 25-32 have been canceled; Claims 19-20 and 23-24 are currently pending before the Examiner.

15           The rejection of claims 19-20, 23-24 and 28-31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 5, 7, 9 and 18-21 of U.S. Patent No. 5,750,110 is withdrawn in view of Applicant's filing of a proper Terminal Disclaimer, Paper No. 43.

20           Claims 19-20 and 23-24 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons  
25           of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. As stated in the last Office Action, the claimed invention is directed to vaccine compositions to protect against infection by Human Immunodeficiency Virus (HIV).

Applicant argues that the PTO has issued other patents to vaccines against pathogens having similar obstacles to those of HIV citing U.S. Patent Nos. 5,789,388 and 5,512,281 (see Paper No. 42, pages 3-4). This is not persuasive. "It is well settled that whether similar claims have been allowed to others is immaterial." See *Ex parte Balzarini*, 21 USPQ2d 1892 at 1897 (Bd. Pat. App. Int, 1991) citing *In re Giolito*, 188 USPQ 645, (CCPA 1976).

Applicant further argues that Applicant's animal model is accepted in the art as reasonably correlating with *in vivo* efficacy in humans, relying upon U.S. Patent No. 5,849,994 (see Paper No. 42, pages 4-8). This is not persuasive for the same reasons set forth in the preceding paragraph. Further, it is well known that, to date, no vaccine has been shown to be effective against HIV. While the Examiner is aware of a number of significant ongoing clinical trials, to date no effective vaccines have been identified. Thus, it is impossible to correlate any results in animal models of HIV infection with efficacy in humans. This was the entire point of the quotation of Haynes et al. If Applicant is aware of any successful vaccine trials for HIV, Applicant is invited to bring them to the Examiner's attention and such evidence would certainly be considered. Evidence that the SHIV/macaque animal model is superior to other models is irrelevant to the question of reasonable correlation with *in vivo* efficacy in humans. Indeed, the very number of proposed animal models for studying HIV infection is itself evidence that those skilled in the art have not accepted any one particular animal model as being reasonably correlative with *in vivo* efficacy in humans. Similarly, the large number of ongoing clinical trials studying potential HIV vaccines is also evidence that those skilled in the art do not readily accept either *in vitro* or *in vivo* animal model data as being reasonably correlating with efficacy in humans.

Further, Applicant argues that "the Examiner cannot reasonably

rely on a statement based on a 1993 scientific article..." referring to the teachings of Haynes et al. (see Paper No. 42, paragraph bridging pages 5-6). This is not persuasive. The Haynes article was published in 1996 and its conclusions stand on their own merit. It is irrelevant that Haynes refers to prior research since it is clear from the reference that Haynes reached the same conclusion in 1996 as was reached in 1993 in spite of three more years of additional research.

As set forth in the last Office Action, it is noted that almost 20 years have elapsed since the identification of the Acquired Immunodeficiency Syndrome (AIDS), more than 15 years since the isolation of HIV-1 and six years since Applicants' filing of their first U.S. application. Considerable resources have been expended throughout that time to find a suitable vaccine for HIV and yet, despite this monumental effort, no such vaccine has as yet been shown to be effective in humans. While several clinical trials are currently in progress, there is no clear indication of a successful vaccine.

Applicants have not provided any convincing evidence that their claimed invention is indeed useful as a therapeutic or preventative for HIV infection and have not provided sufficient guidance to allow one skilled in the art to practice the claimed invention with a reasonable expectation of success and without undue experimentation. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

Serial No. 08/909,879  
Art Unit 1645

5 A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION  
IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE  
EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING  
DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED  
10 UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD,  
THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE  
ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37  
C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE  
ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR  
RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL  
ACTION.

15 Papers relating to this application may be submitted to Group  
1600 by facsimile transmission. The Fax number is (703) 308-4242.  
Please note that the faxing of such papers must conform with the  
Notice published in the Official Gazette, 1096 OG 30, (November 15,  
1989).

20 Any inquiry concerning this communication or earlier  
communications from the Examiner should be directed to Robert D.  
Budens at (703) 308-2960. The Examiner can normally be reached  
Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also  
be reached on alternate Fridays. If attempts to reach the Examiner  
by telephone are unsuccessful, the Examiner's supervisor, Anthony  
Caputa, can be reached at (703) 308-3995.

25 Any inquiry of a general nature or relating to the status of  
this application should be directed to the Group receptionist at  
(703) 308-0196.



Robert D. Budens  
Primary Examiner  
Art Unit 1645

30 rdb  
March 27, 2000